Amendment filed with RCE Attorney Docket No. S63.2N-7132-US03

Remarks

This Amendment is in response to the Advisory Action dated December 8, 2005, and is filed with a Request for Continued Examination. The Final Office Action dated September 11, 2005 objected to the specification; rejected claim 33 citing 35 USC § 112, first paragraph; and rejected claims 33-37 and 39-41 citing 35 USC § 103 over Wang et al. (US 5807520; hereinafter "Wang") in view of Wand et al. (US 5525388; hereinafter "Wand").

By this Amendment, claims 33 and 37 are amended, claim 49 is added and withdrawn claims 42-48 are cancelled without prejudice or disclaimer. Applicants reserve the right to prosecute any cancelled subject matter in a subsequent patent application claiming priority to the immediate application. The specification is also amended. No new matter has been added. Reconsideration in view of the above amendments and following remarks is requested.

Claim Amendments

Claim 33 is amended and the "rotating the mandrel around the mandrel longitudinal axis to rotate the balloon thereon" language, which the Examiner has objected to, has been removed. These limitations are now included as new dependent claim 49.

Withdrawn claims 42-48 are cancelled. Applicants reserve the right to prosecute any cancelled subject matter in a subsequent application claiming priority to the immediate application.

Specification Amendments

The specification is amended to include language directed to mounting a balloon on a mandrel and rotating the mandrel about a longitudinal axis to rotate the balloon thereon. Support for the amendment may be found at least in US 5826588 to Forman, which was incorporated by reference into the immediate application. See page 3, last paragraph. Specifically, support for the added text may be found in Forman at least at column 4, lines 24-28; column 7, lines 1-8, 15-18 and 21-22; and Figures 1 and 5.

Mere rephrasing of a passage does not constitute new matter. Accordingly, a rewording of a passage where the same meaning remains intact is permissible. *In re Anderson*,

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471 F.2d 1237, 176 USPQ 331 (CCPA 1973).

Applicants further note that the Forman patent was cited by the Patent Office during prosecution of the Gonzalez patent (US 6488654; U.S. Application Ser. No. 09/735,692), wherein the Patent Office argued that Forman does teach placing a balloon on a mandrel and rotating the mandrel about the longitudinal axis to rotate the balloon thereon. See page 3 of Office Action dated 4/9/02 from Application No. 09/735692. A copy of the Office Action is attached for convenience.

Claim Rejections - 35 USC § 112

The Office Action rejects claim 33 under 35 USC § 112, first paragraph. Although the rejection is traversed, amendment to claim 33 is believed to render the rejection moot. The "rotating the mandrel around the mandrel longitudinal axis to rotate the balloon thereon" language has been removed. Accordingly, Applicants request withdrawal of the rejection under 35 USC § 112, first paragraph.

Claim Rejections - 35 USC § 103

The Final Office Action rejected claims 33-37 and 39-41 under 35 USC § 103 over Wang in view of Wand. These rejections are traversed.

Applicants assert that Wang in view of Wand do not disclose or suggest all of the limitations of the rejected claims, and that there is no prior art motivation to modify either reference to arrive at the invention of the rejected claims.

Wang teaches a method for forming a balloon comprising the steps of extruding a segment of thermoplastic material, maintaining the center portion at a temperature below the glass transition of the thermoplastic material, drawing the segment to a predetermined length, wherein after the drawing the wall thickness of the center portion does not appreciably change, and expanding the segment in a mold to produce the balloon. See Abstract.

Wand teaches a method for forming a balloon including providing a tubular parison having a thick working section that tapers into thinner wall sections. The parison is molded under heat and pressure, wherein the parison transitions into a balloon with an essentially constant wall thickness. See column 2, lines 30-53.

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Neither Wang nor Wand disclose or suggest "placing the balloon on a mandrel having a longitudinal axis and rotating the balloon," as recited in claim 33.

Although Wang does disclose a mandrel, the disclosure is limited to a discussion in the Background of the Invention section of US 5087394, which teaches a method of stretching a <u>parison</u> prior to blow molding the parison into a balloon. See column 2, lines 53-65. Wang does not teach placing a <u>balloon</u> on a mandrel. Wang further does not teach rotating the balloon thereon.

Similarly, Wand does disclose a mandrel, but disclosure of the mandrel is limited to a discussion of an extrusion method used to form the variable thickness <u>parison</u>. See column 2, line 54-column 3, line 13. The extruded parison is then molded under heat and pressure to form a balloon. See column 3, lines 14-19. Wand does not teach placing a <u>balloon</u> on a mandrel or rotating the balloon.

Neither Wang nor Wand disclose or suggest "positioning a material removal device in contact with an <u>outer surface</u> of at least a section of the rotating <u>balloon to thereby</u> remove balloon material from a portion of at least one of the proximal shaft section and the distal shaft section to form a shaft section having a first portion with a substantially uniform first diameter and a second portion with a substantially uniform second diameter, different than the first diameter," as recited in claim 33.

Wang discloses a method of stretching a tubular parison. See e.g. column 5, lines 1-16. After the stretching process, the tubing is expanded using internal pressure [i.e. molded] to form a balloon. See column 6, lines 50-51. Wang does not discuss removing material from an outer surface of a balloon.

Wand discloses a method of providing a shaped parison 30 and blow molding the shaped parison to form a balloon 12. See column 4, lines 7-23. Wand teaches a method of providing the shaped parison by forming a tubular member and thinning the wall of the tubular member by "machining, abrading or other suitable means." See column 2, lines 45-53. Figure 5 shows the shaped parison, and it is clear that any material removal was performed on an <u>inner surface</u> of the <u>parison</u>. Wand does not disclose removing material from an <u>outer surface</u> of the parison. Wand does not disclose removing material from any portion of a balloon.

The Office Action recites at page 3, "A balloon can be inflated at a room

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temperature, but a balloon preform (parison) is not inflatable at the room temperature." Thus, the Examiner has taken the position that a parison is not a balloon. Applicants agree that a parison is by definition a precursor to a balloon, and therefore not a balloon. Removing material from the parison prevents the removed material from ever becoming part of a balloon. Therefore, Wand clearly does not disclose or suggest removing material from a balloon.

The Office Action further makes an inherency argument with respect to Wang. Wang discloses that it is desirable to have cone and waist walls with uniform thicknesses. See column 2, lines 30-33. The Office Action asserts that, inherently, due to manufacturing tolerances, the uniform thicknesses of the waist portions are actually different from one another. See Office Action page 5, last paragraph.

The fact that a certain result or characteristic <u>may</u> occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is <u>necessarily present</u> in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51.

In this case, nothing in the record shows that a variation in the thicknesses is necessarily present in the Wand device. It is entirely possible that the waist portions will have a uniform thickness, as taught by the reference. Therefore, the inherent possibility of variation due to manufacturing tolerances fails to render claim 33 unpatentable.

Applicants further assert that there is no prior art motivation to modify either reference to arrive at the invention of claim 33. Both Wang and Wand disclose methods of shaping a parison prior to transforming the parison into a balloon via a molding process. Neither reference discloses or suggests removing material from a balloon that has already been formed. Because any shaping operations taught by the applied references are performed on a parison prior to molding, modification of the teachings to first mold the balloon and then perform subsequent shaping operations would change the principle of operation of the prior art methods.

If the proposed modification or combination of the prior art would change the

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principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The mere fact that references <u>can</u> be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

There is no teaching in Wang or Wand that suggests a desirability to perform shaping operations on a balloon after it has been molded. A person of ordinary skill in the art would recognize that a parison is easier to machine than a balloon because the greater wall thickness of the parison imparts greater structural integrity. Further, the subsequent balloon forming step allows for mold-smoothing of any surface irregularities introduced during machining of the parison. For at least the reasons that balloons are thinner and that mold-smoothing does not occur after balloon formation, a person of ordinary skill in the art would not consider it obvious to remove material from the balloon rather than the parison as taught by Wand.

Thus, Applicants assert that claim 33 is patentable over Wang in view of Wand. Claims 34-37 and 39-41 depend from claim 33 and are therefore patentable for at least the reasons discussed with respect to claim 33. Accordingly, Applicants request withdrawal of the rejections under 35 USC § 103.

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Conclusion

Based on at least the foregoing amendments and remarks, Applicants respectfully submit this application is in condition for allowance. Favorable consideration and prompt allowance of claims 34-41 and 49 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Jeremy G. Laabs Registration No.: 53170

Date: 2/17/06

6109 Blue Circle Drive, Suite 2000 Minnetonka, MN 55343-9185 Telephone: (952) 563-3000

Facsimile: (952) 563-3001

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DETAILED ACTION

Receipt is acknowledged of papers submitted for "Preliminary Amendment" on April 20, 2001, paper No. 5. This amendment amends Fig. 7. Amendment papers have been placed of record in the file. The amended claims are examined in this office action.

Cleim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the miligar parties which the applicant regards as his investion.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for falling to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "finer grain" in claim 8 is a relative term which renders the claim indefinite. The term "fines" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections ~ 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action.

A person shall be emitted to a peters unless

(b) the invention was parented or described in a printed publication in this or a foreign examity or in public use or on sale in this country, mean that one year point to the date of application for putent in the United States.

Page 3

 Claims 1 - 3, 10, 12 - 13, 16 - 21 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Forman (USPN 5826588).

With respect to claim 1 and 21, Forman discloses a method of forming a catheter balloon (16), Figs. 1 and 5 column 6 lines 63 - 66, comprising a) providing a balloon (20) formed of a material, column 1 lines 49 - 50, having a proximal end (30), a distal end (32), an expandable section (24), a proximal shaft section and a distal shaft section (shown not labeled), and an outer surface (52); b) placing the balloon on a mandrel (40) having a longitudinal axis (shown not labeled) and rotating the mandrel around the mandrel longitudinal axis to rotate the balloon thereon, column 7 lines 4 - 6; and c) positioning a material removal device (38 with 45) in contact with an outer surface (52) to thereby remove balloon material about the circumferential of the section of the balloon. The catheter tube material is polymethans terephthalate (PET), column 1 lines 50.

With respect to claims 2 – 3, Forman discloses the invention substantially as claimed in the base claim 1. Furthermore, Forman discloses the section of the rotating balloon is the proximal and distal shaft section (shown device position in Fig. 5), column 7 lines 28 – 42, and including causing relative longitudinal displacement between the balloon and the material removal device to remove balloon material.

With respect to claim 10, Forman discloses the invention substantially as claimed in the base claim 1, Furthermore, Forman discloses the material removal device is a laser beam (46).

With respect to claims 12 and 13, Forman discloses the invention substantially as claimed in the base claim 1. Furthermore, Forman discloses the steps of cleaning the balloon of all material deposits resulting from the material removal in column 8 lines 41 - 50.

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With respect to claim 16, Forman discloses the invention substantially as claimed in the base claim 1. Furthermore, Forman discloses the balloon wall thickness is in the range of 0.004-0.0008 inches while the wall thickness away from the main balloon body is in the range of 0.001-0.0025 inches. That is a removal material along a length of about 10% to about 70%.

With respect to claims 17 - 20, Forman discloses the invention substantially as claimed in the base claim 1. Furthermore, Forman discloses in column 9 lines 23 - 32, using a stepping motor (92) and translating plate (90) in two perpendicular direction x and y to precisely remove balloon material. Forman discloses in Figs. 11 and 12, material can be selectively ablated to form an array of channels or grooves in a balloon wall along the each of the tapered sections, column 9 lines 48 - 53.

With regard to claim 30, Forman discloses a catheter belloon comprising an expandable section (24) having a wall thickness is in the range of 0.004-0.0008 inches, column 1 lines 63, a proximal shaft section (30) and distal section (320 each having a wall thickness in the range of 0.001-0.0025 inches, column 2 line 1, wherein the wall thickness of the proximal and distal shaft sections are about 3 to about 10 times greater than the expandable section wall thickness.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may and be obtained though the invention is not identically disolated or described as set forth in section 102 of this title, if the differences between the abbject matter cought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person partially shall in the art to which said subject matter partains. Petentability shall not be negatived by the

Page 5.

Claims 4 – 8, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over
 Forman (USPN 5826588) and further in view of Hoef (USPN 3694280).

With regard to claims 4 and 5. Forman discloses the invention substantially as claimed in the base claim 1. Forman, however, does not disclose using a sharp-edge cutting tool. Hoef discloses a procedure to mechanically cutting balloon material in Fig. 10. It is well known in the art of lathe machining technology to remove material from a spinning work for a desired profile with a cutting tool traversing longitudinally along the axis of the lathe. Hoef also discloses to use a grinder (37) with the lathe to remove material. Therefore, it would have been obvious to one having ordinary skill in the art of lathe machining at the time the invention was made to use a cutting tool with lathe or a grinding tool with lathe, instead of laser beam, as taught by Hoef, to remove the balloon material in a traditional manner without the setup of a high power laser errangement.

With regard to claims 6 - 8, Forman discloses the invention substantially as claimed in the base claim 1. And Hoef discloses to use grinder to remove material on lathe. However, Hoef does not indicate to use a grinder face to remove material on the lathe specifically. It is an operator's choice to orient his grinder axis with respect to the work piece in order to remove the material from the work piece. The grinder axis has been oriented perpendicular or parallel to the work piece in the art of lathe machining technology. It is also well known in the art of grinding technology to have a number of grain grades as the grinder attachments for different applications. They can be interchanged in the process of grinding to achieve the desired final surface finishing condition. Heef does disclose that grinding wheel (37) has a very fine grain surface and may be costed with diamond dust for amount final surface, column 5 lines 60 - 62.

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Therefore, it would have been obvious to one having ordinary skill in the art of lathe machining and grinding disk technology at the time the invention was made to use a grinder, which is capable for being adapted to different grinding surface grain sizes for different finishing as taught by Hoef, and with the grinder axis perpendicular to the work piece in order to remove material.

With regard to claims 14 and 15, Forman discloses the invention substantially as claimed in the base claim 1. However, Forman does not disclose of cutting the balloon catheter to a desired length. Hoef discloses in column 5 lines 49 – 53, using a knife blade (36) to cut desired length. Therefore, it would have been obvious to one having ordinary skill in the art of lathe machining and its cutting tool technology at the time the invention was made to use a knife mounted on the lathe tool assembly to precisely cut the work piece to its desired length.

Claims 9 and 22 - 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over
 Forman (USPN 5826588) and further in view of Markling (USPN 4321226).

With regard to claim 9, Forman discloses the invention substantially as claimed in the base claim 1. Forman, however, does not disclose to use a grinder to remove balloon material.

Markling discloses in Fig. 4 a grinding assembly to remove material, column 5 lines 16 - 21.

Therefore, it would have been obvious to one having ordinary skill in the art of lathe/grinding machining at the time the invention was made to use a grinding tool with lathe, instead of laser beam, as taught by Markling, to remove the balloon material in a traditional manner without the setup of a high power laser arrangement.

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with respect to claims 22 and 23, Forman discloses a system for removing insterial from a polymer tube to form a medical device, inflatable balloon catheter used for percutaneous transhuminal angioplasty, column 1 lines 9Figs. 1 and 5, comprising a mandrel (40) having a longitudinal axia, a first end (30) and a second end (32); a collet having a gripping end (42) and a second end (44), the gripping end gripping the first end of the mandrel; a lathe spindle rotate the mandrel, column 7 line 6 (spindle not shown); a polymor tube (16) having a longitudinal axis, a first end (260 a second end (28) and a lumen therethrough, disposed about the second end of the mandrel (44); and a material removal device (38). Forman does not disclose a lathe spindle and a turning tool secured to the material removal device and configured to bring the material removal device in contact with the polymeric tube. Markling discloses in Fig.4, a spindle (34) to rotate the gripping end of the collet and turning tool (46) secured to the material removal device (42) and to bring the material removal device in contact with the polymeric tube, column 5 lines 14:—21. Therefore, it would have been obvious to one having ordinary skill in the art of lathe matching at the time the invention was made to use a spindle to hold the work piece and a hand wheel to bring the material removal device in contact with the polymeric tube.

With regard to claim 28, Forman and Markling disclose the invention substantially as claimed in the base claim 22. Furthermore, Forman discloses that the material removal device is a laser beam, Fig. 5. Therefore, it would have been obvious to one having ordinary skill in the art of anaterial removal at the time the invention was made to use laser to remove precisely the amount of the material from the eatherer tube surface for manufacturing the balloon.

Pega 8

 Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Forman (USPN 5825588) and fürther in view of Pande (USPN 4753765).

Forman discloses the invention substantially as claimed in the base claim 1. Forman, bowser, does not disclose to use chamical solvent to remove balloon material. Pande disclose to use solvent dissolving for removing catheter material, column 4 lines 4f8 -51. Therefore, it would have been obvious to one having ordinary skill in the art of using chemical solvent in the polymer technology, as taught by Pande, instead of laser beam, to remove the balloon material in a chemical process without the setup of a high power laser afrangement.

 Claims 24 - 27 are rejected under 35 U.S.C. 103(a) as being impatentable over Forman (USPN 5826588) and further in view of Markling (USPN 4321226) and Hoef (USPN 3694280).

With respect to claims 24 - 27, Forman and Markling disclose the invention substantially as claimed in the base claim 22. Forman and Markling, however, do not disclose that mandrel has an external taper along the longitudinal axis. Hoef shows in Fig. 4, mandrel (23) has tapered section (25) and the material removal device is a sharp edge cutting tool (36) and rotating abrasive surface (37). Therefore, it would have been obvious to one having ordinary skill in the art of holding to reinforcing and section of the tubing along the longitudinal axis by tapering to an larger diameter section; and in the art of effectively removing material on the lather by using a knife and a rotating abrasive surface, as taught by Hoef.

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Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Forman (USPN 5826588) and further in view of further in view of Markling (USPN 4321226) and Fands (USPN 4753765).

Forman and Markling disclose the invention substantially as claimed in the base claim 22. Forman and Markling, however, do not use chemical solvent to remove balloon material.

Pande disclose to use solvent dissolving for removing eatheter material, column 4 lines 4f8 –51. Therefore, it would have been obvious to one having ordinary skill in the art of using chemical solvent in the polymer technology, as taught by Panda, instead of laser beam, to remove the balloon material in a chemical process without the setup of a high power laser arrangement.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jorgensen (USPN 5647848), wand et al. (USPN 5525388), Ozasa (USPN 5334146), Euteneuer (USPN 4952357).

Jorgensen disclose a high strength low compliance composite balloon for balloon catherers. The balloon includes an elastomeric skin having a constraining structure affixed thereto. The constraining structure allows radial expension between an un-inflated diameter and an inflated diameter. The minimum inflation pressure can be calculated based on the chosen elastomer.

Wand et al. disclose a balloon for a dilatation eathersr having a cylindrically shaped working section and tapered end sections, which have essentially the same wall thickness. The balloon is formed from a tubular parison, which has a central thick walled portion.

Page 10

Ozasa discloses a catheter balloon made of polymer, comprising a cylindrical portion of a substantially uniform diameter and tapered portions at the front and rear of the cylindrical section with different slopes.

Euteneuer discloses a method for forming a balloon for use in a balloon catheter by depositing a film over the exterior surface of a substrate. The film includes a phrality of layers in which one of the layers is a polyamide and another is made of a metallic material, which heats in response to the application of electromagnetic energy. The substrate is removed to leave a balloon in the desired shape.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Han Lieh Liu whose telephone number is 703-305-0860. The examiner can normally be reached on 7:30 to 17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy S. Thorpe can be reached on 703-308-0102. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0861.

Han Lieh Liu March 27, 2002 CHARVES G. FREAY PRIMARY DOMINER

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